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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/424,048

02/24/2000

GRAHAM VESEY

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12/05/2001

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EXAMINER

FIELDS, IESHA P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/05/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,048

Applicant(s)

VESEY ET AL.

Examiner

Ilesha P Fields

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 20) ☐ Other: ____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's Amendment filed on October 25, 2001 has been entered.

Claim Rejections - 35 USC § 112

1. Claim 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's Amendment to the claim.
2. Claims 20-23 are under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's have indicated a willingness to perfect the deposit requirement upon an indication that the claims are allowable. However, until the strain is deposited

and all rights irrevocable removed upon the granting of a patent, this rejection is maintained.

Claim Rejections - 35 USC § 102

3. Claims 1-8 and 16-17 are rejected under 35 U.S.C. 102 (b) as being anticipated by McDonald et al.

The claims are drawn to a method of producing IgG antibodies to the surface of *Cryptosporidium* oocysts which are capable of eliciting an immune response in an animal.

McDonald et al. (Parasitology 110:1995 pp. 259-98) disclose a method of purifying *Cryptosporidium* oocysts including the pretreatment of oocysts (See Materials and Methods Section; especially parasites section). McDonald et al. further disclose that the oocysts were both isolated and purified. McDonald et al. further disclose that the IgG antibody was produced specifically against the oocysts wall (See Material and Methods Monoclonal Section).

Applicant's have asserted that the only reference to monoclonal antibodies in the McDonald et al. reference is in the Material and Methods Section. Applicant's have further asserted that McDonald et al. immunized mice with oocyst homogenates and not purified oocyst.

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Applicant's arguments have been carefully considered but they are not deemed persuasive.

The entire publication of McDonald et al. discloses the use of monoclonal antibodies (See Entire Document; especially Title and Summary Sections). McDonald et al. clearly discloses that the "study was designed to examine the reactivity of three mAbs developed against *C. parvum* oocysts antigens" (See Introduction Section). The argument that McDonald et al. immunized mice with oocyst homogenates is not persuasive because McDonald et al. clearly teaches that the oocysts in the study were **isolated and purified** (See Material and Methods Section). The reference does not teach that the oocysts were disrupted as the Applicant has concluded. Moreover, claim 1 does not recite this limitation. With respect to claims 16-17, McDonald et al clearly discloses IgG mAb (See Material and Methods Section: especially monoclonal antibodies section in which 2C3, an IgG mAb is disclosed).

Claim Rejections - 35 USC § 103

4. Claims 9-15 and 18- 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al in view of Riggs et al.

The claims are drawn to a method of producing isolated IgG1 antibodies which are reactive to the surface of *Cryptosporidium* oocysts.

The teachings of McDonald et al. are set forth above.

Applicant's have asserted that McDonald et al. does not teach the claimed invention and further that the McDonald and Riggs et al. references were incorrectly

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combined. Applicant's further assert that the Riggs et al. reference is concerned with obtaining purified sporozoites not oocysts or oocysts surface antigens.

Applicant's arguments have been carefully considered but they are not deemed persuasive.

As the Applicant has indicated on page 5, last paragraph, Riggs et al teach of immunizing an animal with purified sonicated whole oocysts. As stated previously, it is the Examiner's position that because Riggs et al. teach that one group of animals were immunized with purified oocysts it can be reasonably concluded that the oocyst preparation contained separation of at least part of the Cryptosporidium oocysts wall from internal sporozoites (i.e. oocysts surface antigen) thereby meeting all of the limitations recited in claim 9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

December 3, 2001



MARK NAVARRO
PRIMARY EXAMINER